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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,601	04/20/2004	Victor P. Chu	DCS-9173	5537
34500	7590	02/03/2006	EXAMINER KUMAR, SHAILENDRA	
DADE BEHRING INC. LEGAL DEPARTMENT 1717 DEERFIELD ROAD DEERFIELD, IL 60015			ART UNIT 1621	PAPER NUMBER

DATE MAILED: 02/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	Applicant(s)	
10/828,601	CHU ET AL.	
Examiner	Art Unit	
SHAIENDRA - KUMAR	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12 and 13 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 6-9, 14-17 and 19 is/are rejected.
- 7) ☒ Claim(s) 3, 5, 10, 11, 18 and 20-28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This office action is in response to applicants' communication filed on 11/21/05.

Claims 1-28 are pending in this application.

Rejection of claims 1-4, 6-9, 14-19, and 20-22 under 35 USC 102(b) over Registry number 107924-26-5, is hereby withdrawn, subsequent to applicants' arguments.

Rejection of claims 1-28 under 35 USC 112, 2<sup>nd</sup> paragraph is hereby withdrawn subsequent to applicants' amendments.

#### ***Claim Rejections - 35 USC § 112***

1. Claim 7 recites the limitation "Y" in line 1. There is insufficient antecedent basis for this limitation in the claim. Note this claim depends from claim 1, and claim 1 does not define Y.

#### ***Claim Rejections - 35 USC § 102***

1. Claims 1-2, 4, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Kostowski et al (Acta Poloniae Pharmaceutica, 1978).

Kostowski et al, page 380, compounds RC<sub>6</sub> anticipates instant claimed compounds, when in the instant claims, R1, R2 and R3 are hydrogen, L is methylene and Z is primary amine.

#### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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6. Claims 1-2, 4, 6, 8, 9, 14-17, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over combined teachings of Kostowski et al and Stanley et al (US 5,288,498).

Kostowski et al are teaching structurally similar compounds and pharmaceutical composition as claimed herein, see for example, page 380, various compounds. The difference between the reference and herein claimed composition is that the reference does not teach polymer conjugation to the lidocaine compounds.

Stanley et al is teaching that polymer conjugation to the drug molecule is old in the art, see for example, column 21, Table 2, line 39, and column 11, lines 8-11.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the compounds of Kostowski et al and conjugate to a polymer as taught by Stanley et al, because the latter reference is expressly teaching that conjugation to the drug molecule like lidocaine is old in the art. Note that positional isomers are prima facie obvious, absent evidence to the contrary. Ex parte Mowry 91 USPQ 219.

7. Claims 3, 5, 10, 11, 18, 20-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Claims 12-13 are free of art and are allowable.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAIENDRA -. KUMAR whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Thur 8:00-5:30, Alt Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571)272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SHAIENDRA - KUMAR  
Primary Examiner  
Art Unit 1621

S.Kumar  
1/31/06